Sotera WIRELESS

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5 510(K) SUMMARY

Date prepared	June 11, 2013
Name	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.373.4841; F. 858.427.4639
Contact person	Eben Gordon Senior Director, Regulatory
Trade name	ViSi Mobile Monitoring System
Common name	Vital signs monitor
Regulation Name	Cardiac Monitor Including Cardiotachometer and Rate Alarm
Classification number	21 CFR 870.2300
Product code	MWI, DRT, DXN, DQA, FLL
Regulatory class	II
Predicate devices	ViSi Mobile Monitoring System; K112478 (Clearance: 3/27/2012) CNAP Monitor 500i, 500at; K082599 (Clearance: 10/17/2008)
Description	The ViSi Mobile Monitoring System is a lightweight, body-worn vital signs monitor featuring a high resolution, full color touch screen display, with visual and audible alarms and alerts. The ViSi Mobile Monitor is designed to continuously non-invasively measure ECG, heart rate, SpO2, blood pressure, pulse rate, respiration rate, and temperature. The ECG, SpO2, and Respiration waveforms are viewable on demand. The ViSi Mobile Monitoring System is capable of one-time and continuous NIBP measurements.
Indications for use	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult (18 years or older) patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments. Continuous non-invasive blood pressure (cNIBP) testing has not been conducted on ambulatory patients.
Summary of substantial equivalence	The ViSi System has the following similarities and differences with the indicated predicate devices:

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- Intended use – The ViSi System has the same vital sign monitoring intended use as the ViSi System and CNAP Monitors. The cNIBP measurement of the ViSi System is the same as the CNAP Monitor.

- Device Performance – The modified ViSi System with intermittent NIBP MAP and cNIBP measurements have been clinically validated to meet the same performance requirements (mean error ≤ ± 5 mmHg; standard deviation ≤ 8 mmHg) as outlined in the consensus standards for automated non-invasive blood pressure monitors.

- Technology – The ViSi System is unchanged from it predicate submission except for the display of intermittent NIBP MAP readings and the continuous non-invasive blood pressure (cNIBP) measurements.

  The intermittent NIBP MAP measurement is based on the same technology as is currently in the cleared ViSi System and is equivalent to the CNAP Monitor. The ViSi's MAP measurement has been validated by comparison to an intra-arterial reference and meets the performance requirements of ISO 81060-2.

  The ViSi's cNIBP measurement has a different principle of operation from that of the CNAP Monitor predicate device. Both methods are similar in that pressure is determined on a beat-to –beat basis and are joint solutions employing automatic calibration to NIBP measurements.

  The question of effectiveness of the cNIBP measurement has been addressed by the clinical performance validation to the requirements of ISO 81060-2, an equivalent consensus standard to which the CNAP Monitor meets (i.e. AAMI/ANSI SP10).

The safety and effectiveness of the design elements implemented into the ViSi System have been confirmed by their compliance to the prevailing standards. The ViSi System has demonstrated compliance with the following consensus standards: IEC 60601-1-8, IEC 80601-2-30, IEC 62304, ISO 81060-2, and IEC 62366.

General Safety and Effectiveness Concerns – The instructions for use for the ViSi System contains the necessary cautions and warnings to provide for safe and effective use of the device.

The ViSi System has successfully undergone functional testing to demonstrate equivalence to the predicate devices. The following quality assurance measures were applied to the device: Risk analysis, Requirements review, Code inspections, Verification and validation, Bench testing, and Clinical performance testing.

The ViSi System have been tested and found to comply with recognized performance standards for medical devices. The results of all the testing demonstrate that the ViSi System is safe, effective, complies with the appropriate medical device standards, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 7, 2013

Sotera Wireless, Inc.
Attn: Mr. Eben Gordon
Sr. Director, Regulatory Affairs
9444 Waples St., Suite 280
San Diego, CA 92121

Re: K130709
Trade/Device Name: Visi Mobile Monitoring System, Model 92-10010
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (Two)
Product Code: MWI, DRT, DXN, DQA and FLL
Dated: September 30, 2013
Received: October 1, 2013

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE

510(k) Number (if known): _K130709_____

Device Name: _____ViSi Mobile Monitoring System _____

Indications for Use:

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult (18 years or older) patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Continuous non-invasive blood pressure (cNIBP) testing has not been conducted on ambulatory patients.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
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